

109TH CONGRESS
1ST SESSION

H. R. 4245

To provide for programs and activities with respect to pandemic influenza,
and for other purposes.

IN THE HOUSE OF REPRESENTATIVES

NOVEMBER 7, 2005

Mr. LEWIS of California (for himself, Mr. REGULA, Mr. FRELINGHUYSEN, Mr. DREIER, Mrs. BONO, Mr. ISSA, and Mr. DOOLITTLE) introduced the following bill; which was referred to the Committee on Energy and Commerce, and in addition to the Committees on Resources and Agriculture, for a period to be subsequently determined by the Speaker, in each case for consideration of such provisions as fall within the jurisdiction of the committee concerned

A BILL

To provide for programs and activities with respect to
pandemic influenza, and for other purposes.

1 *Be it enacted by the Senate and House of Representa-*
2 *tives of the United States of America in Congress assembled,*

3 **SECTION 1. SHORT TITLE; TABLE OF CONTENTS.**

4 (a) SHORT TITLE.—This Act may be cited as the
5 “Influenza Preparedness and Prevention Act of 2005”.

6 (b) TABLE OF CONTENTS.—The table of contents of
7 this Act is as follows:

Sec. 1. Short title; table of contents.

TITLE I—VACCINE AND ANTIVIRAL PURCHASING

- Sec. 101. Influenza antivirals supply.
 Sec. 102. Procurement of vaccines for the Strategic National Stockpile.
 Sec. 103. Procurement of essential supplies.

TITLE II—VACCINE PRODUCTION CAPACITY

- Sec. 201. Liability protections for pandemics, epidemics, and biodefense countermeasures.
 Sec. 202. Vaccine buyback program.
 Sec. 203. Approval of vaccines.
 Sec. 204. Establishment of Office of Safety Evaluation and Pandemic Preparedness.

TITLE III—PANDEMIC PREPAREDNESS

- Sec. 301. Public education on pandemic influenza and preparedness.
 Sec. 302. Educational efforts and grants.
 Sec. 303. Domestic surveillance of wild birds.
 Sec. 304. Research at the National Institutes of Health.
 Sec. 305. Research at the Centers for Disease Control and Prevention.
 Sec. 306. Global surveillance.
 Sec. 307. Proposal for international fund to support pandemic influenza control.
 Sec. 308. Pandemic influenza and animal health.

TITLE IV—STATE AND LOCAL INFRASTRUCTURE

- Sec. 401. State preparedness plan.

TITLE V—GENERAL PROVISIONS

- Sec. 501. Authorization of appropriations.

1 **TITLE I—VACCINE AND**
 2 **ANTIVIRAL PURCHASING**

3 **SEC. 101. INFLUENZA ANTIVIRALS SUPPLY.**

4 (a) IN GENERAL.—The Secretary of Health and
 5 Human Services (referred to in this Act as the “Sec-
 6 retary”) shall establish a stockpile of anti-virals to use for
 7 rapid response to an influenza outbreak.

8 (b) AMOUNT.—The stockpile established under sub-
 9 section (a) shall be of sufficient quantity to treat not less
 10 than 25 percent of the population of the United States.

1 **SEC. 102. PROCUREMENT OF VACCINES FOR THE STRA-**
2 **TEGIC NATIONAL STOCKPILE.**

3 Subject to development and testing of potential vac-
4 cines for pandemic influenza, including possible pandemic
5 avian influenza, the Secretary shall determine the min-
6 imum number of doses of vaccines needed to prevent infec-
7 tion during at least the first wave of pandemic influenza
8 for health professionals (including doctors, nurses, mental
9 health professionals, pharmacists, veterinarians, labora-
10 tory personnel, epidemiologists, virologists, and public
11 health practitioners), core public utility employees, and
12 those persons expected to be at high risk for serious mor-
13 bidity and mortality from pandemic influenza, and take
14 immediate steps to procure this minimum number of doses
15 for the Strategic National Stockpile.

16 **SEC. 103. PROCUREMENT OF ESSENTIAL SUPPLIES.**

17 The Secretary shall, as soon as is practicable, take
18 action to procure for the Strategic National Stockpile es-
19 sential supplies (including ventilators, syringes, res-
20 pirators, surgical masks, and gloves) that may be needed
21 in the event of a pandemic.

TITLE II—VACCINE PRODUCTION CAPACITY

**SEC. 201. LIABILITY PROTECTIONS FOR PANDEMICS,
EPIDEMICS, AND BIODEFENSE COUNTER-
MEASURES.**

Part B of title III of the Public Health Service Act is amended by inserting after section 319F–2 (42 U.S.C. 247d–6b) the following:

**“SEC. 319F–3. LIABILITY PROTECTIONS FOR PANDEMIC AND
EPIDEMIC PRODUCTS AND SECURITY COUN-
TERMEASURES.**

“(a) **AUTHORITY.**—As provided for in subsection (b), and subject to paragraph (1)(C) of such subsection, a manufacturer, distributor, administrator, or health care provider shall be immune, under Federal and State law, from suit or liability caused by or arising out of the covered application of a covered countermeasure pursuant to a declaration by the Secretary described in subsection (b)(2).

“(b) **LITIGATION MANAGEMENT.**—

“(1) **LIMITATION ON CAUSE OF ACTION.**—

“(A) **NO CAUSE OF ACTION IN CERTAIN
CASES.**—

“(i) **IN GENERAL.**—No cause of action shall exist against a manufacturer, dis-

1 tributor, administrator, or a health care
2 provider described in subsection (a) for
3 claims of loss arising out of, relating to, or
4 resulting from the covered application of a
5 covered countermeasure that is deployed
6 pursuant to a declaration by the Secretary
7 described in paragraph (2).

8 “(ii) RULE OF CONSTRUCTION.—For
9 purposes of this section, the term ‘arising
10 out of, relating to, or resulting from’ shall
11 not be construed to apply to a loss that
12 has no causal relationship with the admin-
13 istration or use of a covered counter-
14 measure.

15 “(B) RULE.—

16 “(i) SUBSEQUENT INJURY.—The pro-
17 tections provided for in subsection (a) and
18 subparagraph (A) of this paragraph shall
19 apply to a covered application of a covered
20 countermeasure regardless of the date of
21 alleged injury.

22 “(ii) PRIVATE DONATION OR SALE.—
23 The protections provided for in subsection
24 (a) and subparagraph (A) of this para-
25 graph shall apply to a covered application

1 of a covered countermeasure regardless of
2 whether the covered countermeasure is on
3 the commercial market, so long as the cov-
4 ered countermeasure is deployed in a dec-
5 laration described in paragraph (2) and
6 the Secretary does not specifically prohibit
7 such private donation or sale in such dec-
8 laration.

9 “(C) POTENTIAL LIABILITY UPON DETER-
10 MINATION.—

11 “(i) IN GENERAL.—A manufacturer,
12 distributor, or administrator of a covered
13 countermeasure or a health care provider
14 who administers a covered countermeasure
15 shall not be immune under subsection (a)
16 or exempted from a cause of action under
17 subparagraph (A) if—

18 “(I) in the case of a manufac-
19 turer or distributor, the Secretary
20 makes an affirmative determination
21 under subparagraph (D)(ii) against
22 such manufacturer or distributor; or

23 “(II) in the case of an adminis-
24 trator or health care provider, the ad-
25 ministrator or health care provider

1 acts with willful misconduct as that
2 term is defined in regulations promul-
3 gated by the Secretary and the Attor-
4 ney General.

5 “(D) INVESTIGATION AND DETERMINA-
6 TION BY SECRETARY CONCERNING ACTIONS
7 AGAINST MANUFACTURERS, OR DISTRIBUTU-
8 TORS.—

9 “(i) INVESTIGATION BY SEC-
10 RETARY.—A petitioner seeking a deter-
11 mination under clause (ii) may petition the
12 Secretary to investigate allegations of will-
13 ful misconduct against a manufacturer or
14 distributor for a loss arising out of, relat-
15 ing to, or resulting from a covered applica-
16 tion of a covered countermeasure as pro-
17 vided for in subparagraph (A). The peti-
18 tion shall demonstrate to the Secretary
19 that such petitioner has suffered a loss as
20 a direct result of the willful misconduct of
21 a manufacturer or distributor. The deci-
22 sion whether or not to undertake the inves-
23 tigation shall be within the Secretary’s dis-
24 cretion and shall not be subject to judicial
25 review.

1 “(ii) DETERMINATION BY SEC-
2 RETARY.—To make an affirmative deter-
3 mination under this subparagraph, the
4 Secretary shall find, by clear and con-
5 vincing evidence, that—

6 “(I) the manufacturer or dis-
7 tributor of a covered countermeasure
8 violated a provision of the Federal
9 Food, Drug, and Cosmetic Act (21
10 U.S.C. 301 et seq.) or this Act, and
11 such violation is material to the loss
12 alleged; and

13 “(II) in violating either such Act,
14 such manufacturer or distributor
15 acted with willful misconduct and
16 such misconduct—

17 “(aa) caused the covered
18 countermeasure to present a sig-
19 nificant or unreasonable risk to
20 human health; and

21 “(bb) proximately caused
22 the injury alleged by the peti-
23 tioner.

24 “(iii) NOTICE AND HEARING.—If the
25 Secretary finds that an affirmative deter-

1 mination will likely be made under clause
2 (ii), the Secretary shall undertake an ac-
3 tion in accordance with section 556 of title
4 5, United States Code.

5 “(iv) EFFECT OF DETERMINATION.—
6 Subject to subsection (c) and subpara-
7 graph (C) of this paragraph, the only ex-
8 ception to the immunity from suit and li-
9 ability of manufacturers or distributors of
10 a covered countermeasure provided for in
11 subsection (a) and subparagraph (A) of
12 this paragraph shall be for actions against
13 a manufacturer or distributor as provided
14 for in such subparagraph (A) that are sub-
15 ject to an affirmative determination under
16 clause (ii).

17 “(v) JUDICIAL REVIEW.—

18 “(I) MANUFACTURERS OR DIS-
19 TRIBUTORS.—At any time prior to the
20 90th day following an affirmative de-
21 termination by the Secretary under
22 subparagraph (D)(ii), any manufac-
23 turer or distributor subject to such an
24 affirmative determination may file a
25 petition with the United States Court

1 of Appeals for the District of Colum-
2 bia, for a judicial review of such de-
3 termination. The court’s review under
4 this subclause shall be limited in scope
5 to a review of the record to determine
6 whether the Secretary’s actions were
7 unsupported by substantial evidence
8 or unwarranted by the facts. A copy
9 of the petition shall be transmitted by
10 the clerk of the court to the Secretary
11 or other officer designated by the Sec-
12 retary for that purpose. The Secretary
13 thereupon shall file in the court the
14 record of the findings on which the
15 Secretary based his or her determina-
16 tion. The filing of a petition under
17 this clause shall automatically stay
18 the Secretary’s determination for the
19 duration of the judicial proceeding.

20 “(II) PETITIONERS.—Any person
21 who brought a petition to the Sec-
22 retary under subparagraph (D)(i)
23 may, at any time prior to the 90th
24 day following a determination by the
25 Secretary under subparagraph (D)(ii),

1 file a petition with the United States
2 Court of Appeals for the District of
3 Columbia Circuit, for a judicial review
4 of such determination. Notwith-
5 standing any other provision of law,
6 the court's review under this sub-
7 clause shall be limited in scope to a
8 review of the record to determine
9 whether the Secretary's actions were
10 arbitrary, capricious, or an abuse of
11 discretion.

12 “(vi) TOLLING OF STATUTE OF LIM-
13 TATIONS.—The computation of the statute
14 of limitations for any action against a
15 manufacturer or distributor described in
16 this subparagraph shall not include any pe-
17 riod of time that occurs prior to the time
18 at which an affirmative determination by
19 the Secretary under this subparagraph be-
20 comes final, and upon—

21 “(I) the expiration of the 90-day
22 period following such determination if
23 the aggrieved party does not seek ju-
24 dicial review of such determination
25 under clause (ii); or

1 “(II) the conclusion of a judicial
2 review proceeding under clause (ii),
3 including any appeal.

4 “(vii) PROCEDURES FOR ACTIONS
5 AGAINST MANUFACTURERS AND DISTRIBUTORS.—An action that is allowed under
6 this paragraph shall be brought in the
7 United States District Court. No jury trial
8 shall be allowed. If the plaintiff prevails,
9 the court may award only compensatory
10 damages, and not punitive damages.

12 “(E) REGULATORY AUTHORITY.—Not later
13 than 90 days after the date of enactment of
14 this section, the Secretary, in consultation with
15 the Attorney General, shall promulgate regula-
16 tions to define what actions by a manufacturer,
17 distributor, administrator, or health care pro-
18 vider of a covered countermeasure shall be
19 deemed to constitute ‘willful misconduct’ for
20 purposes of clause (i). In promulgating such
21 regulations, the Secretary shall consider the na-
22 ture of the actual or potential public health
23 emergency, the timing and extent of any cov-
24 ered countermeasure program, and any other
25 circumstances the Secretary determines to be

1 significant, so that any civil actions permitted
2 under this subsection will not adversely affect
3 public health. The Secretary may specify the
4 period of time for which such regulations apply.

5 “(F) PROCEDURES FOR SUIT AGAINST AD-
6 MINISTRATORS AND HEALTH CARE PRO-
7 VIDERS.—An action that is permitted under
8 this subsection shall be brought in United
9 States District Court. A plaintiff in such action
10 shall specify in his or her complaint each action
11 or omission that allegedly constitutes willful
12 misconduct. No jury trial shall be allowed. No
13 discovery will be allowed before the court rules
14 on any motion to dismiss or a motion for sum-
15 mary judgment. If a plaintiff prevails, the court
16 may award only compensatory damages, and
17 not punitive damages.

18 “(G) SCOPE.—Subparagraph (C) shall
19 apply regardless of whether the action or liabil-
20 ity described in subsection (a) or the claim de-
21 scribed in subparagraph (A) of this paragraph
22 arises from the covered application by the Fed-
23 eral Government or by any person.

24 “(2) DECLARATION BY THE SECRETARY.—

1 “(A) IN GENERAL.—The Secretary may
2 issue a declaration, pursuant to this paragraph,
3 that an actual or potential public health emer-
4 gency makes it advisable that a covered coun-
5 termeasure be manufactured, tested, or de-
6 ployed to a covered individual.

7 “(B) SECURITY COUNTERMEASURE OR
8 QUALIFIED PANDEMIC OR EPIDEMIC PROD-
9 UCT.—The Secretary shall specify in a declara-
10 tion under subparagraph (A) the covered coun-
11 termeasure to be sold by, purchased from, or
12 donated by a manufacturer or drawn from the
13 Strategic National Stockpile.

14 “(C) EFFECTIVE PERIOD.—The Secretary
15 shall specify in a declaration under subpara-
16 graph (A) the beginning and the ending dates
17 of the effective period of the declaration. The
18 Secretary may subsequently amend such dec-
19 laration to shorten or extend such effective pe-
20 riod if the new ending date is after the date on
21 which the declaration is amended.

22 “(D) PUBLICATION.—The Secretary shall
23 promptly publish each declaration under sub-
24 section (a) and any amendments in the Federal
25 Register.

1 “(c) ACTIONS BY AND AGAINST THE UNITED
2 STATES.—

3 “(1) ACTIONS BY THE UNITED STATES.—Noth-
4 ing in this section shall be construed to abrogate or
5 limit any right, remedy, or authority that the United
6 States or any agency thereof may possess under any
7 other provision of law.

8 “(2) IMMUNITY.—The United States shall be
9 immune from an action or liability caused by or aris-
10 ing out of the covered application of a covered coun-
11 termeasure, described in subsection (b)(1)(A), to the
12 same extent as a health care provider, a manufac-
13 turer, a distributor, or an administrator of a covered
14 countermeasure.

15 “(d) SEVERABILITY.—If any provision of this section,
16 or the application of such provision, to any person or cir-
17 cumstance is held to be unconstitutional, the remainder
18 of this section and the application of such provisions to
19 any person or circumstance shall not be affected thereby.

20 “(e) DEFINITIONS.—In this section:

21 “(1) ADMINISTRATOR.—The term ‘adminis-
22 trator’ includes a State or local government, a per-
23 son employed by the State or local government, or
24 other person, who supervised or administered a pro-
25 gram with respect to the administration, dispensing,

1 distribution, or provision of a security counter-
2 measure or a qualified pandemic or epidemic prod-
3 uct, including a person who has established require-
4 ments, provided policy guidance, or supplied tech-
5 nical or scientific advice assistance or provides a fa-
6 cility to administer or use a covered countermeasure
7 in accordance with a designation under subsection
8 (b)(2).

9 “(2) COVERED APPLICATION.—The term ‘cov-
10 ered application’ means design, development, clinical
11 testing and investigation, manufacture, labeling, dis-
12 tribution, sale, purchase, donation, dispensing, pre-
13 scribing, administration, licensing, or use of a quali-
14 fied pandemic or epidemic product or a security
15 countermeasure.

16 “(3) COVERED COUNTERMEASURE.—The term
17 ‘covered countermeasure’ means a qualified pan-
18 demic or epidemic product or a security counter-
19 measure.

20 “(4) COVERED INDIVIDUAL.—The term ‘cov-
21 ered individual’ means one or more categories of in-
22 dividuals who the Secretary has identified in a dec-
23 laration under subsection (b)(2).

24 “(5) DEPLOYED.—The term ‘deployed’ means
25 manufactured, tested, distributed, sold, purchased,

1 donated, dispensed, prescribed, administered, li-
2 censed, or used.

3 “(6) HEALTH CARE PROVIDER.—The term
4 ‘health care provider’ means a person, including a
5 volunteer, who is licensed or authorized under State
6 law to distribute, prescribe, administer, or dispense,
7 a security countermeasure or a qualified pandemic
8 or epidemic product.

9 “(7) LOSS.—The term ‘loss’ means death, in-
10 jury, illness, disability, condition, medical moni-
11 toring, or loss of or damage to property, including
12 business interruption loss.

13 “(8) MANUFACTURER.—The term ‘manufac-
14 turer’ includes—

15 “(A) a contractor or subcontractor of a
16 manufacturer;

17 “(B) a supplier or licensor of any product,
18 intellectual property, service, research tool, or
19 component of the qualified pandemic or epi-
20 demic product or security countermeasure; and

21 “(C) any or all of the parents, subsidiaries,
22 affiliates, successors, and assigns of a manufac-
23 turer.

24 “(9) QUALIFIED PANDEMIC OR EPIDEMIC PROD-
25 UCT.—The term ‘qualified pandemic or epidemic

1 product’ means a drug (as such term is defined in
2 section 201(g)(1) of the Federal Food, Drug, and
3 Cosmetic Act (21 U.S.C. 321(g)(1)), biological prod-
4 uct (as such term is defined by section 351(i) of this
5 Act), device (as such term is defined by section
6 201(h) of the Federal Food, Drug and Cosmetic Act
7 (21 U.S.C. 321(h)), that is manufactured, used, de-
8 signed, developed, modified, licensed, or procured to
9 diagnose, mitigate, prevent, treat, or cure a pan-
10 demic or epidemic or limit the harm such pandemic
11 or epidemic might otherwise cause or a serious or
12 life-threatening disease or condition caused by such
13 a product, that—

14 “(A)(i) is approved or cleared under chap-
15 ter V of the Federal Food, Drug, and Cosmetic
16 Act or licensed under section 351 of this Act;

17 “(ii) is authorized for emergency use in ac-
18 cordance with section 564 of the Federal Food,
19 Drug, and Cosmetic Act;. or

20 “(iii) is the object of research for possible
21 use to treat, identify, or prevent harm from
22 pandemic flu; and

23 “(B) is specified in a declaration under
24 subsection (b)(2).

1 “(10) PERSON.—The term ‘person’ includes an
2 individual, partnership, corporation, association, en-
3 tity, or public or private corporation, including a
4 Federal, State, or local government agency or de-
5 partment.

6 “(11) SECURITY COUNTERMEASURE.—The
7 term ‘security countermeasure’ has the meaning
8 given such term in section 319F–2(c)(1)(B).”.

9 **SEC. 202. VACCINE BUYBACK PROGRAM.**

10 (a) IN GENERAL.—The Secretary shall establish an
11 influenza vaccine buyback protocol under which the Sec-
12 retary may enter into buyback contracts with manufactur-
13 ers of influenza vaccine to purchase such manufacturers’
14 excess stocks of influenza vaccine so long as such vaccine
15 has been manufactured in accordance with the rec-
16 ommendations of the Advisory Committee for the produc-
17 tion of seasonal influenza vaccine.

18 (b) MANUFACTURERS.—The Secretary shall have the
19 discretion to award buyback contracts under subsection
20 (a) to several influenza vaccine manufacturers in a man-
21 ner consistent with the goal of providing stability in the
22 influenza vaccine market, as long as the Federal Govern-
23 ment purchases not more than 50 percent of the excess
24 influenza vaccine stock of any single manufacturer at mar-
25 ket price.

1 **SEC. 203. APPROVAL OF VACCINES.**

2 (a) CRITERIA FOR FAST-TRACK APPROVAL.—

3 Promptly after the date of the enactment of this Act, the
4 Secretary of Health and Human Services, acting through
5 the Commissioner of Food and Drugs, shall consult with
6 potential manufacturers of vaccines against pandemic in-
7 fluenza to develop specific criteria for fast-track approval
8 of such vaccines.

9 (b) PROVISIONS RELATING TO INFLUENZA VACCINE
10 MANUFACTURERS.—Chapter IX of the Federal Food,
11 Drug, and Cosmetic Act (21 U.S.C. 391 et seq.) is amend-
12 ed by adding at the end the following:

13 **“SEC. 909. PROVISIONS RELATING TO INFLUENZA VACCINE**
14 **MANUFACTURERS.**

15 “(a) ASSISTANCE AND TECHNICAL TRAINING
16 BRANCH.—The Secretary shall expand and strengthen the
17 activities of the Manufacturer Assistance and Technical
18 Training Branch at the Center for Biologics Evaluation
19 and Research of the Food and Drug Administration to
20 provide for the dissemination of information, and to pro-
21 vide technical guidance, to entities seeking to comply with
22 regulations of the Secretary relating to the production of
23 biologic materials, particularly influenza vaccine.

24 “(b) PROVISIONS RELATED TO THE EMERGENCY AC-
25 QUISSION OF VACCINES.—

1 “(1) INCREASED COMMUNICATION.—The Food
2 and Drug Administration shall carry out activities to
3 increase communication between the agency and the
4 scientific community regarding vaccine development
5 and regulation, including participation in con-
6 ferences on the science related to infectious diseases,
7 influenza, biologic manufacturing, and other issues
8 as determined appropriate by the Director of the
9 Center for Biologics Evaluation and Research.

10 “(2) REGULATORY ROADMAP.—The Commis-
11 sioner, in consultation with the Director of the Cen-
12 ters for Disease Control and Prevention, the Sec-
13 retary, and other agencies or participants as deter-
14 mined appropriate by the Secretary, shall develop a
15 regulatory roadmap to address the following issues
16 surrounding emergency use authorization of influ-
17 enza vaccine, as determined by the Secretary during
18 a public health emergency involving an actual or im-
19 minent outbreak of naturally occurring or engi-
20 neered seasonal influenza:

21 “(A) Policies for the emergency use au-
22 thorization of influenza vaccine that is produced
23 and sold in other countries so that such vaccine
24 may be imported into the United States by the

1 United States government during a vaccine
2 shortage.

3 “(B) Policies for the facilitation of the dis-
4 tribution of any such vaccine imported into the
5 United States during a vaccine shortage, in-
6 cluding the interstate transportation, allocation
7 and equitable distribution of vaccine among
8 high priority populations (as defined by the Ad-
9 visory Committee on Immunization Practices
10 and the Centers for Disease Control and Pre-
11 vention) during an emergency use situation.

12 “(C) Policies for the communication and
13 coordination of a response to an emergency use
14 authorization with State and local health de-
15 partments, including guidelines for notification
16 of such entities in such situations.

17 “(D) Policies for the emergency use au-
18 thorization of vaccines that are in clinical devel-
19 opment in both the United States and other
20 countries, including clarification of IND proto-
21 cols for such vaccines, particularly those using
22 new vaccine development technologies.

23 “(3) CONSULTATION.—In developing the road-
24 map under paragraph (2), the Commissioner shall
25 solicit input from private and nonprofit stakeholders,

1 including State and local health officials, and such
 2 input shall include recommendations for developing
 3 emergency use authorization guidelines that main-
 4 tain the scientific and regulatory standards of the
 5 Food and Drug Administration.”.

6 **SEC. 204. ESTABLISHMENT OF OFFICE OF SAFETY EVALUA-**
 7 **TION AND PANDEMIC PREPAREDNESS.**

8 Title XXI of the Public Health Service Act (42
 9 U.S.C. 300aa–1 et seq.) is amended by adding at the end
 10 the following:

11 **“Subtitle 3—Office of Safety Eval-**
 12 **uation and Pandemic Prepared-**
 13 **ness**

14 **“SEC. 2141. ESTABLISHMENT; DEFINITIONS.**

15 “(a) ESTABLISHMENT.—There is established in the
 16 Office of the Secretary the Office of Safety Evaluation and
 17 Pandemic Preparedness, to be headed by the Director of
 18 Safety Evaluation and Pandemic Preparedness.

19 “(b) DEFINITIONS.—In this subtitle:

20 “(1) The term ‘Director’ means the Director of
 21 Safety Evaluation and Pandemic Preparedness.

22 “(2) The term ‘Office’ means, unless otherwise
 23 specified, the Office of Safety Evaluation and Pan-
 24 demic Preparedness.

1 “(3) The term ‘qualified pandemic or epidemic
2 product’ has the meaning given to that term in sec-
3 tion 4101 of title 28, United States Code.

4 “(4) The term ‘security countermeasure’ has
5 the meaning given to that term in section 4101 of
6 title 28, United States Code.

7 **“SEC. 2142. AUTHORITIES.**

8 “(a) IN GENERAL.—With respect to qualified pan-
9 demic or epidemic products and security countermeasures,
10 the Director shall—

11 “(1) conduct or support safety research, includ-
12 ing research on—

13 “(A) acute and chronic adverse reactions,
14 including with respect to subpopulations;

15 “(B) components of such products and
16 countermeasures, including additives, adjuvants,
17 and preservatives; and

18 “(C) delivery mechanisms;

19 “(2) conduct or support long- and short-term
20 monitoring, including with respect to new and al-
21 tered products and countermeasures;

22 “(3) conduct or support research across a range
23 of disciplines, including molecular genetics, toxi-
24 cology, pharmacokinetics, cell biology, neurology, im-
25 munology, and epidemiology;

1 “(4) conduct or support research to address
2 issues raised in claims of injury brought before the
3 Secretary or the Attorney General of the United
4 States;

5 “(5) develop and test hypotheses about poten-
6 tial adverse reactions;

7 “(6) evaluate, on a regular basis, the compli-
8 ance of health care providers and the manufacturers
9 of such products and countermeasures with Federal
10 requirements for reporting adverse reactions related
11 to such products and countermeasures;

12 “(7) conduct or support research to evaluate re-
13 ports of injury following administration of such
14 products and countermeasures for the purpose of de-
15 veloping tests to prescreen individuals and sub-
16 populations at greater risk of injury; and

17 “(8) conduct or support research to evaluate bi-
18 ological mechanisms of injury for the purpose of
19 eliminating or reducing the risk of such injury
20 through better prescreening tools or through modi-
21 fication of such products and countermeasures.

22 “(b) PERSONNEL.—In carrying out this subtitle, the
23 Director—

24 “(1) may not employ at management positions
25 any individual—

1 “(A) who has been employed by the Cen-
2 ters for Disease Control and Prevention or the
3 Food and Drug Administration to carry out any
4 function relating to monitoring, or research on,
5 adverse reactions related to a licensed vaccine;
6 or

7 “(B) who has been employed by a vaccine
8 manufacturer; and

9 “(2) shall ensure that all personnel assigned to
10 carry out functions relating to monitoring, or re-
11 search on, adverse reactions related to qualified pan-
12 demic or epidemic products or security counter-
13 measures do not have any related professional, fa-
14 milial, or financial conflict of interest.

15 “(c) GRANT APPLICANTS.—In awarding any grant
16 relating to research on adverse reactions related to quali-
17 fied pandemic or epidemic products or security counter-
18 measures, the Director—

19 “(1) shall ensure that the applicant for the
20 grant does not have—

21 “(A) any financial conflict of interest that
22 might compromise the research findings, such
23 as holding a related patent or having a family
24 member who holds a related patent; or

1 “(B) any conflict of interest resulting from
2 the applicant’s association with an entity with
3 direct or indirect financial interest in the out-
4 comes of the research, such as receiving money
5 or an in-kind contribution from a manufacturer
6 of such products or countermeasures; and

7 “(2) shall disqualify any applicant having any
8 contractual relationship with, or receiving any fund-
9 ing from, any person with a direct or indirect inter-
10 est in the outcomes of the research.”.

11 **TITLE III—PANDEMIC** 12 **PREPAREDNESS**

13 **SEC. 301. PUBLIC EDUCATION ON PANDEMIC INFLUENZA** 14 **AND PREPAREDNESS.**

15 (a) IN GENERAL.—The Secretary of Health and
16 Human Services, acting through the Director of the Cen-
17 ters for Disease Control and Prevention, shall develop and
18 implement a public education campaign about pandemic
19 influenza and preparedness.

20 (b) CERTAIN REQUIREMENTS.—The education and
21 outreach activities under subsection (a) shall include—

22 (1) efforts to distribute information concerning
23 the potential need for general vaccination; education
24 materials on personal precautionary measures;

1 (2) the development of a strategy with the busi-
2 ness community to provide information about the
3 economic disruptions that may arise during a pan-
4 demic period;

5 (3) consulting with State and local governments
6 to inform the public on procedures that may be
7 taken during a pandemic period, including with re-
8 spect to vaccine and antiviral distributions and quar-
9 antines.

10 **SEC. 302. EDUCATIONAL EFFORTS AND GRANTS.**

11 Part B of title III of the Public Health Service Act
12 (42 U.S.C. 243 et seq.) is amended by inserting after sec-
13 tion 319B the following:

14 **“SEC. 319B–1. IMMUNIZATION EDUCATIONAL EFFORTS AND**
15 **GRANTS.**

16 “(a) IN GENERAL.—The Director of the Centers for
17 Disease Control and Prevention, in conjunction with State
18 and local health departments, shall revise and expand the
19 influenza-related educational materials to the Centers for
20 Disease Control and Prevention, and facilitate the use of
21 such materials by health care providers and patients. The
22 Director is authorized to coordinate such educational ef-
23 forts with nonprofit provider and patient advocacy groups.

24 “(b) INFLUENZA VACCINE EDUCATION AND OUT-
25 REACH.—

1 “(1) IN GENERAL.—In order to achieve an opti-
2 mal balance in the influenza vaccine market, and to
3 ensure that the recommendations of the Advisory
4 Committee on Immunization Practices to the Cen-
5 ters for Disease Control and Prevention for vaccine
6 administration are carried out to the maximum ex-
7 tent possible, the Director of the Centers for Disease
8 Control and Prevention, in conjunction with State
9 and local health departments, shall carry out influ-
10 enza immunization education and outreach activities
11 that target physicians and other health care pro-
12 viders, health insurance providers, health care insti-
13 tutions and patients, particularly those in high pri-
14 ority populations (as defined by the Advisory Com-
15 mittee on Immunization Practices and the Centers
16 for Disease Control and Prevention) (referred to in
17 this section as ‘high priority populations’).

18 “(2) TYPES OF ACTIVITIES.—The education
19 and outreach activities under paragraph (1) shall in-
20 clude—

21 “(A) activities to encourage voluntary par-
22 ticipation in influenza vaccination programs,
23 with the goal of increasing overall influenza
24 vaccination rates in the United States, achiev-
25 ing full influenza vaccination of all high priority

1 populations, and full use of each season’s influ-
 2 enza vaccine supply;

3 “(B) the provision of information on influ-
 4 enza prevention;

5 “(C) activities to increase the number of
 6 healthcare providers who receive influenza vac-
 7 cines each year; and

8 “(D) other influenza educational efforts
 9 determined appropriate by the Director.

10 “(c) GRANTS.—The Director of the Centers for Dis-
 11 ease Control and Prevention may award grants to State
 12 and local health departments to carry out activities to en-
 13 courage individuals, particularly those from high priority
 14 populations, to seek out influenza vaccinations.

15 “(d) COLLABORATION.—State and local health de-
 16 partments that receive grants under subsection (b) are en-
 17 couraged to collaborate on projects with physicians and
 18 other health care providers, health insurance providers,
 19 health care institutions, and groups representing high pri-
 20 ority populations.”.

21 **SEC. 303. DOMESTIC SURVEILLANCE OF WILD BIRDS.**

22 (a) IN GENERAL.— The United State Geological Sur-
 23 vey, working in coordination with the United States Fish
 24 and Wildlife Service, the National Park Service, and other

1 relevant agencies, shall carry out an interagency effort to
2 detect avian influenza in wild birds.

3 (b) TYPES OF ACTIVITIES.—The efforts under sub-
4 section (a) shall include—

5 (1) preparing standard guidelines for routine
6 and systematic monitoring of wild birds;

7 (2) developing a uniform protocol for reporting
8 mortality events; developing instructions for safe
9 handling and shipping of specimens to diagnostic fa-
10 cilities;

11 (3) training for field personnel in procedures;
12 and

13 (4) reporting on finding back to the field.

14 **SEC. 304. RESEARCH AT THE NATIONAL INSTITUTES OF**
15 **HEALTH.**

16 The Director of the National Institutes of Health (re-
17 ferred to in this section as the “Director of NIH”), in
18 collaboration with the Director of the Centers for Disease
19 Control and Prevention, and other relevant agencies, shall
20 expand and intensify human and animal research, with re-
21 spect to influenza, on—

22 (1) vaccine development and manufacture, in-
23 cluding strategies to increase immunological re-
24 sponse;

- 1 (2) effectiveness of inducing heterosubtypic im-
- 2 munity;
- 3 (3) antigen-sparing studies;
- 4 (4) antivirals, including minimal dose or course
- 5 of treatment and timing to achieve prophylactic or
- 6 therapeutic effect;
- 7 (5) side effects and drug safety of vaccines and
- 8 antivirals in subpopulations;
- 9 (6) alternative routes of delivery of vaccines,
- 10 antivirals, and other medications as appropriate;
- 11 (7) more efficient methods for testing and de-
- 12 termining virus subtype;
- 13 (8) protective measures;
- 14 (9) modes of influenza transmission;
- 15 (10) effectiveness of masks, hand-washing, and
- 16 other non-pharmaceutical measures in preventing
- 17 transmission;
- 18 (11) improved diagnostic tools for influenza;
- 19 and
- 20 (12) other areas determined appropriate by the
- 21 Director of NIH.

22 **SEC. 305. RESEARCH AT THE CENTERS FOR DISEASE CON-**
23 **TROL AND PREVENTION.**

24 The Director of the Centers for Disease Control and
25 Prevention, in collaboration with other relevant agencies,

1 shall expand and intensify research, with respect to influ-
2 enza, on—

3 (1) historical research on prior pandemics to
4 better understand pandemic epidemiology, trans-
5 mission, protective measures, high-risk groups, and
6 other lessons that may be applicable to future pan-
7 demic;

8 (2) communication strategies for the public dur-
9 ing pandemic influenza, taking into consideration
10 age, racial and ethnic background, health literacy,
11 and risk status;

12 (3) changing and influencing human behavior
13 as it relates to vaccination;

14 (4) population-based surveillance methods to es-
15 timate influenza infection rates and rates of out-
16 patient illness;

17 (5) vaccine effectiveness;

18 (6) systems to monitor vaccination coverage lev-
19 els and adverse events from vaccination; and

20 (7) other areas determined appropriate by the
21 Director of the Centers for Disease Control and Pre-
22 vention.

23 **SEC. 306. GLOBAL SURVEILLANCE.**

24 The Director of the Centers for Disease Control and
25 Prevention, in collaboration with the Department of State

1 and other relevant agencies, shall expand and intensify the
2 efforts of the Global Disease Detection Initiative. The Sec-
3 retary shall increase the number of international public
4 health sites and staff abroad in countries impacted by pan-
5 demic influenza to conduct disease identification and
6 intervention activities, provide critical public health exper-
7 tise to countries in need, train international collaborators
8 to recognize and respond to influenza and other disease
9 threats, and improve communication capabilities. The Di-
10 rector of the Centers for Disease Control and Prevention
11 shall conduct a feasibility study and plan for the contain-
12 ment of a human pandemic flu outbreak abroad.

13 **SEC. 307. PROPOSAL FOR INTERNATIONAL FUND TO SUP-**
14 **PORT PANDEMIC INFLUENZA CONTROL.**

15 (a) IN GENERAL.—The Secretary should submit to
16 the Director of the World Health Organization a proposal
17 to study the feasibility of establishing a fund, (referred
18 to in this section as the “Pandemic Fund”) to support
19 pandemic influenza control and relief activities conducted
20 in countries affected by pandemic influenza, including
21 pandemic avian influenza.

22 (b) CONTENT OF PROPOSAL.—The proposal sub-
23 mitted under subsection (a) shall describe, with respect
24 to the Pandemic Fund—

25 (1) funding sources;

1 (2) administration;

2 (3) application process by which a country may
3 apply to receive assistance from such Fund;

4 (4) factors used to make a determination re-
5 garding a submitted application, which may in-
6 clude—

7 (A) the gross domestic product of the ap-
8 plicant country;

9 (B) the burden of need, as determined by
10 human morbidity and mortality and economic
11 impact related to pandemic influenza and the
12 existing capacity and resources of the applicant
13 country to control the spread of the disease;
14 and

15 (C) the willingness of the country to co-
16 operate with other countries with respect to
17 preventing and controlling the spread of the
18 pandemic influenza; and

19 (5) any other information the Secretary deter-
20 mines necessary.

21 (c) USE OF FUNDS.—Funds from any Pandemic
22 Fund established as provided for in this section shall be
23 used to complement and augment ongoing bilateral pro-
24 grams and activities from the United States and other
25 donor nations.

1 **SEC. 308. PANDEMIC INFLUENZA AND ANIMAL HEALTH.**

2 (a) IN GENERAL.—The Secretary of Agriculture shall
3 expand and intensify efforts to prevent pandemic influ-
4 enza, including possible pandemic avian influenza.

5 (b) REPORT.—Not later than 180 days after the date
6 of enactment this Act, the Secretary of Agriculture shall
7 submit to Congress a report that describes the anticipated
8 impact of pandemic influenza on the United States agri-
9 culture industry.

10 (c) ASSISTANCE.—The Secretary of Agriculture, in
11 consultation with the Secretary of Health and Human
12 Services, the World Health Organization, and the World
13 Organization for Animal Health, shall provide domestic
14 and international assistance with respect to pandemic in-
15 fluenza preparedness to—

16 (1) support the eradication of infectious animal
17 diseases and zoonosis;

18 (2) increase transparency in animal disease
19 states;

20 (3) collect, analyze, and disseminate veterinary
21 data;

22 (4) strengthen international coordination and
23 cooperation in the control of animal diseases; and

24 (5) promote the safety of world trade in ani-
25 mals and animal products.

TITLE IV—STATE AND LOCAL INFRASTRUCTURE

SEC. 401. STATE PREPAREDNESS PLAN.

(a) IN GENERAL.—As a condition of receiving funds from the Centers for Disease Control and Prevention or the Health Resources and Services Administration related to bioterrorism, a State shall—

(1) designate an official or office as responsible for pandemic influenza preparedness;

(2) submit to the Director of the Centers for Disease Control and Prevention (referred to in this section as the “Director”) a Pandemic Influenza Preparedness Plan described under subsection (b); and

(3) have such Preparedness Plan approved in accordance with this section.

(b) PREPAREDNESS PLAN.—

(1) IN GENERAL.—The Pandemic Influenza Preparedness Plan required under subsection (a) shall address—

(A) human and animal surveillance activities, including capacity for epidemiological analysis, isolation and subtyping of influenza viruses year-round, including for avian influenza

1 among domestic poultry, and reporting of infor-
2 mation across human and veterinary sectors;

3 (B) methods to ensure surge capacity in
4 hospitals, laboratories, outpatient healthcare
5 provider offices, medical suppliers, and commu-
6 nication networks;

7 (C) assisting the recruitment and coordina-
8 tion of national and State volunteer banks of
9 healthcare professionals;

10 (D) distribution of vaccines, antivirals, and
11 other treatments to priority groups, and mon-
12 itor effectiveness and adverse events;

13 (E) networks that provide alerts and other
14 information for healthcare providers and orga-
15 nizations at the National, State, and regional
16 level;

17 (F) communication with the public with re-
18 spect to prevention and obtaining care during
19 pandemic influenza;

20 (G) maintenance of core public functions,
21 including public utilities, refuse disposal, mor-
22 tuary services, transportation, police and fire-
23 fighter services, and other critical services;

24 (H) provision of security for—

1 (i) first responders and other medical
2 personnel and volunteers;

3 (ii) hospitals, treatment centers, and
4 isolation and quarantine areas;

5 (iii) transport and delivery of re-
6 sources, including vaccines, medications
7 and other supplies; and

8 (iv) other persons or functions as de-
9 termined appropriate by the Secretary;

10 (I) the acquisition of necessary legal au-
11 thority for pandemic activities;

12 (J) integration with existing national,
13 State, and regional bioterrorism preparedness
14 activities or infrastructure;

15 (K) coordination among public and private
16 health sectors with respect to healthcare deliv-
17 ery, including mass vaccination and treatment
18 systems, during pandemic influenza; and

19 (L) coordination with Federal pandemic in-
20 fluenza preparedness activities.

21 (2) UNDERSERVED POPULATIONS.—The Pan-
22 demic Influenza Preparedness Plan required under
23 subsection (a) shall include a specific focus on sur-
24 veillance, prevention, and medical care for tradition-
25 ally underserved populations, including low-income,

1 racial and ethnic minority, immigrant, and unin-
2 sured populations.

3 (c) APPROVAL OF STATE PLAN.—

4 (1) IN GENERAL.—The Director shall develop
5 criteria to rate State Pandemic Influenza Prepared-
6 ness Plans required under subsection (a) and deter-
7 mine the minimum rating needed for approval.

8 (2) TIMING OF APPROVAL.—Not later than 90
9 days after a State submits a State Pandemic Influenza
10 Preparedness Plan as required under sub-
11 section (a), the Director shall make a determination
12 regarding approval of such Plan.

13 (d) REPORTING OF STATE PLAN.—All Pandemic In-
14 fluenza Preparedness Plans submitted and approved
15 under this section shall be made available to Congress,
16 State officials, and the public as determined appropriate
17 by the Director.

18 (e) ASSISTANCE TO STATES.—The Centers for Dis-
19 ease Control and Prevention and the Health Resources
20 and Services Administration may provide assistance to
21 States in carrying out this section, or implementing an
22 approved State Pandemic Influenza Preparedness Plan,
23 which may include the detail of an officer to approved do-
24 mestic pandemic sites or the purchase of equipment and
25 supplies.

1 (f) WAIVER.—The Director may grant a temporary
2 waiver of 1 or more of the requirements under this section.

3 **TITLE V—GENERAL PROVISIONS**

4 **SEC. 501. AUTHORIZATION OF APPROPRIATIONS.**

5 For the purpose of carrying out this Act and the
6 amendments made by this Act, there are authorized to be
7 appropriated such sums as may be necessary for each of
8 the fiscal years 2006 through 2010.

